

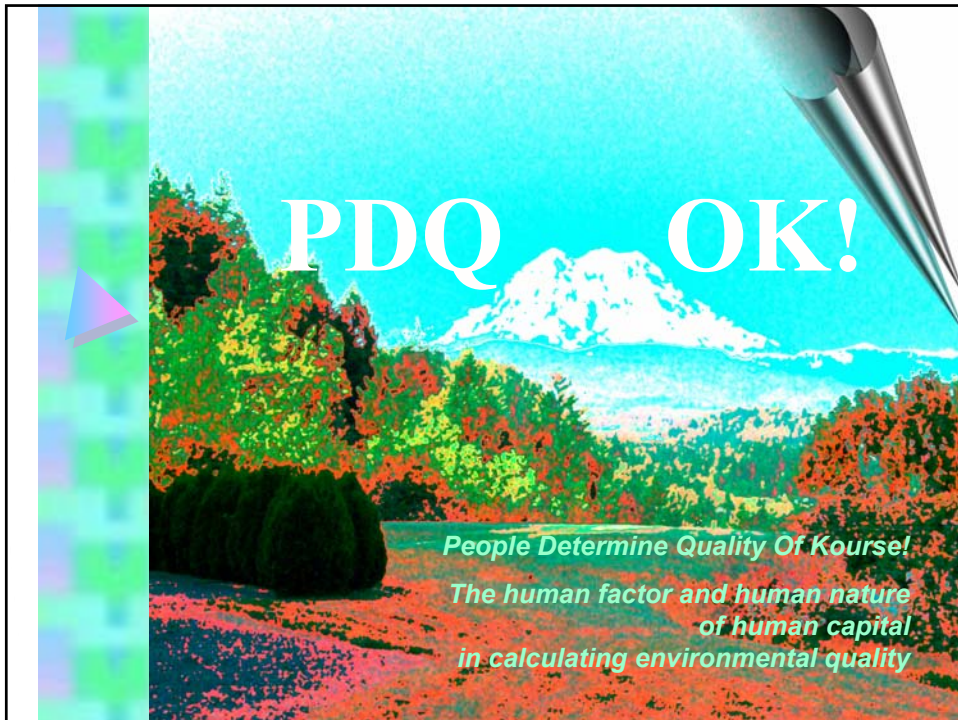
**Part 6- Session Presentations for the EPA 23rd Annual National
Conference on Managing Environmental Quality
Systems**

April 13-16, 2004 Tampa, Florida

Workshop: People Determine Quality of Kourse!

**Workshop: Principles and Practices for Correct Sampling and
the Impact on Statistical Data Quality**

**Workshop: Practical Applications and Benefits of ISO 9001 to
Current Quality Systems**





Mission of EPA

...protect human health and safeguard the natural environment upon which life depends...

**Information Quality Guidelines
EPA/260R-02-008**



Quality for Environmental Programs

The primary goal of the EPA is for environmental programs and decisions to be supported by data of the type and quality needed and expected for their intended use.

**EPA Quality Manual for Environmental Programs
EPA Order 5360.1 A2**



Quality for Environmental Information

The Office of Environmental Information Quality Staff develops quality management practices and tools to enable individual quality systems to be planned, implemented, documented and assessed.

EPA Order 5360.1 A2



Quality for Environmental Data

Many quality system activities involving environmental data operations are inherently performed by personnel.

EPA Order 5360.1 A2



Quality for Environmental Decisions

Environmental data, whether from direct measurements or models, data bases or literature, is collected, compiled, and evaluated for decisions.

EPA Order 5360.1 A2



Quality for Environmental Protection

“Environmental quality stands on the human factor and human nature of human capital, joined at the hip.”

*Nisqually BOW
(Book of Waters)*



Human Factor

**Common denominator
of data input and decision output**



Human Nature

**Constant determinator
of data input and decision output**



Human Capital

Civil demonstrator
of data input and decision output



Equation of Relativity

$$E = mc^2$$

Albert
Einstein

Elementary Environmentalism

E = Environment

m = mankind

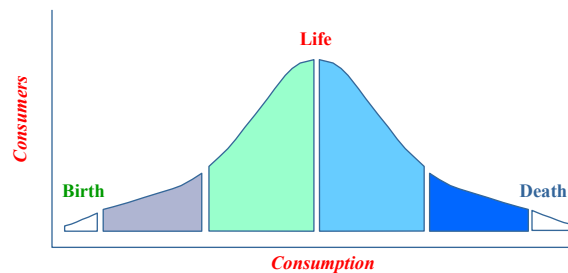
c^2 = rate of consumption

Albert
Envirostein

Nisqually Bow of Consumption

*“Preservation is a function of
humans over time.”*

*Nisqually BOW
(Book of Waters)*





Environment defined

“Your surroundings – air, water, land, natural resources, humans & their interrelation – from within the organization out to the global system.”

Inside ISO 14000



Environmental Indicators defined

Scientific measurements that help measure over time the state of air, water, and land resources, pressures on those resources, and resulting effects on ecological condition and human health.

**EPA Draft Report on the Environment
Glossary of Terms**



Sustainable Development defined

Sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs.

*“Our Common Future”
Brundtland Report*

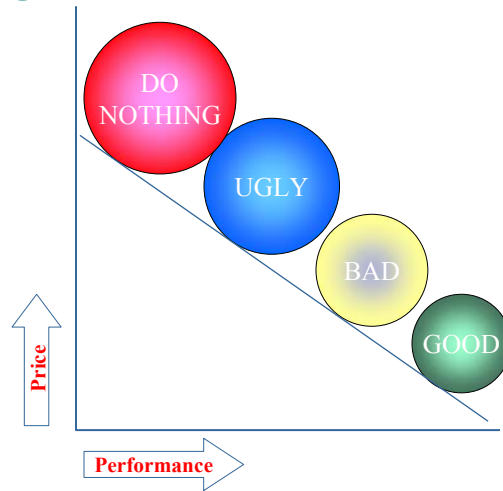


Sustainability defined

*“Take what you need,
leave enough for tomorrow.”*

*Nisqually BOW
(Book of Waters)*

Economy of Scale, Sustainably Speaking



PDQ OK! (Rainbow Consultants)

19

CROW Sustainability Awards

🏆 Big S.D.

Significant watershed community action.

🏆 Little S.D.

Significant watershed community product.

00041 OSI
(ALL4ONE Ohop Sustainability Index)

PDQ OK! (Rainbow Consultants)

20



Nisqually BOW Awards

🏆 **Big S.D.**

Seventh generation risk decision.

🏆 **Little S.D.**

Seventh generation risk thinking.

*00041 OSI
(ALL4ONE Ohop Sustainability Index)*



Watershed Sustainability Metrics

- **Real objectives**
- **Honest targets**
- **Full commitment**
- **Known liabilities**
- **Calibrated community**

Watershed Sustainability Calendar



PDQ OK! (Rainbow Consultants)

23

Watershed Sustainabilisms

- **Legacy = History+Habitat+Humanity+Heritage**
- **7th Generation objectives (7 GO's)**
- **First Generation targets (GO Fers)**
- **ECHO (Each Citizen Has Opportunity)**
- **Environmentalism by default**

PDQ OK! (Rainbow Consultants)

24



“The world should focus on protecting the environment and on how to live in dignity on the globe in the future.”

***Hans Corell
United Nations Legal Counsel
announcing his retirement***



“I had a math teacher tell me when I was in high school that two data points are a hint, and three are a trend.”

***An Environment of Deception
by Lisa Heinzerling
February 25, 2004***



Exercises in environmental quality

1. **Stretch existing environmental indicators to fit sustainability**
2. **Scrunch sustainability indicators to fit a watershed world**
3. **Sketch out benchmarks to calibrate a sustainable watershed community**



enjoy



ABSTRACT

The primary goal of the EPA is for environmental programs and decisions to be supported by data of the type and quality needed and expected for their intended use. The Office of Environmental Information Quality Staff develops quality management practices and tools to enable individual quality systems to be planned, implemented, documented and assessed. Many quality system activities involving environmental data operations are inherently performed by personnel. Environmental data, whether from direct measurements or models, data bases or literature, is collected, compiled, and evaluated for decisions. (EPA Quality Manual for Environmental Programs, EPA Order 5360.1 A2). In every instance, the quality of the information relies in some way on the human factor and human nature of human capital.

This workshop openly discusses how the human factor is critical to data input and decision output for sustainability. It explores the influence of human nature on environmental quality using real life characterization of wisdom and folly within a managed watershed. It is an open forum on the human factor and human nature as undervalued human capital in quality systems and methodologies, uncertainty in measurements, innovations in quality tools and techniques and as educators for future sustainability indicators.

This workshop is an opportunity for participants to develop performance indicators for sustainability to be used by a watershed community. The CROW, Citizens Reclaiming the Ohop Watershed, is highlighted as a test case watershed community for three exercises: 1) Stretch existing environmental indicators to fit sustainability; 2) Scrunch sustainability indicators to fit a watershed world; and, 3) Sketch out benchmarks to calibrate a sustainable watershed community.

Source documents for sustainability indicators are provided for reference use; such as the EPA Index of Watershed Indicators; EPA Strategy for Water Quality Standards and Criteria; EPA Environmental Management System Implementation Policy; United Nations Agenda 21; United Nations Millennium Declaration (Resolution 55/2); et al.

The workshop facilitators, Don Sayre and Steve Pruitt (Rainbow Consultants) are leading sustainable development in and for the Ohop Watershed, the heart of the Nisqually River Watershed from Mt. Rainier to Puget Sound, Washington State.



✚ **Integrated Sustainability Options ONE4ALL**

Inside ISO 14000

✚ **PDQ OK!**

✚ **Sustainable as Wisdom**

Wind, rain, dirt, fire and the ego in between

✚ **Equation Earth, the Sum of All Things**

✚ **Nisqually Book of Waters (BOW)**

✚ **The 8 ALs of Human Capital**

✚ **Nine Lives by Varjac, Paul**

✚ **The Culture of Extinction, a NOW Debate**

Food for Thought Training

Breakfast with Champions

Let's Do Lunch Workshops

Dinner and a Seminar

Principles and Practices for Correct Sampling and the Impact on Statistical Data Quality

by
Dr. Patricia L. Smith
Alpha Stat Consulting Company
And
Texas Tech University

Alpha@AlphaStat.com

EPA Conference on Managing Environmental Quality
Tampa, Florida
April 2004

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

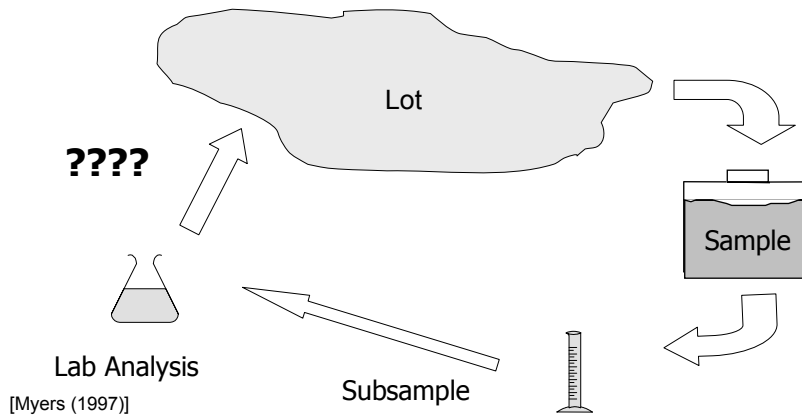
Topics

- **Overview of the Principle of Correct Sampling with Examples.**
- **Hands-on Sampling Exercise.**
- **Discussion and Comparison of Sampling Methods and Results.**
- **Impact on Statistical Data Quality.**

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

The Goal of Good Sampling...

**Figure out what's going on
in the whole Lot (or population). How?**

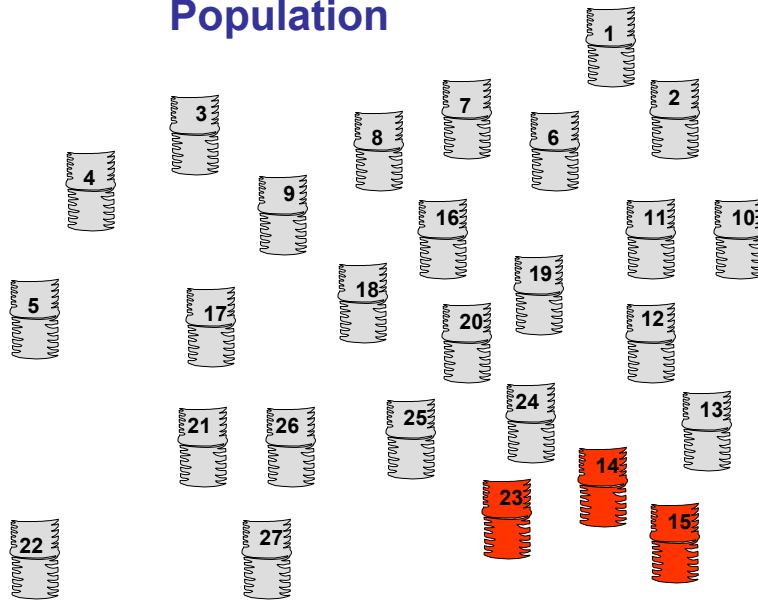


Random Sampling

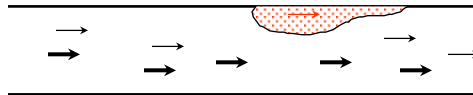
**Every element (unit) in the population has
the same chance of being in the
sample.**

This ensures that the sample is unbiased.

Population



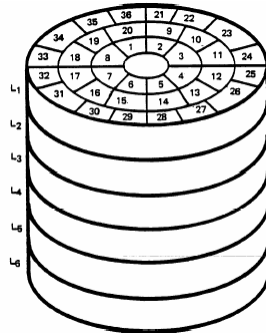
© 2004 Alpha Stat Consulting Company, All Rights Reserved.



**A grab sample.
(a convenient sample)**

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

EPA SW 846



EPA SW-846, Chap. 9, Page 75
<http://www.epa.gov/sw-846>

- Section the material.
- Number the sections.
- Take a “random” sample.

How?

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

PROBLEMS WITH BULK SAMPLING

- The units or elements in the lot (population) are not individually identifiable. So how do we define the sample?
- How do we physically extract the sample?
- How do we ensure that the sample integrity is preserved?

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

Pierre Gy's Principle of Correct Sampling

- **All constituent elements of the lot have an equal opportunity of being in the sample.**
(generalization of random sampling)
- **The integrity of the sample is preserved both during and after sampling.**
(important to maintain chemical and physical properties of interest)

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

The Principle of Correct Sampling is simple, right?

“Unfortunately, this almost self-evident proscription is often completely ignored in the design of sampling methods and devices, which often leads to enormous bias in sample estimates. Such unrecognized biases have led to the economic failure of numerous projects.”

Richard A. Bilonick, Technometrics 36 (1994) 218-219.

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

Consequences of Incorrect Sampling

- Sampling bias is introduced.
- Sampling variation is increased, sometimes substantially, beyond the unavoidable statistical sampling variation.

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

Three Errors resulting from Incorrect Sampling

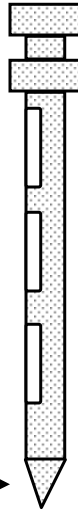
- A **Delimitation Error** occurs when the sampling increment has not been correctly defined theoretically.
- An **Extraction Error** occurs when the increment defined has not been correctly recovered.
- A **Handling Error** occurs when the sample has not been preserved during or after sampling.

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

Delimitation Error and Extraction Error

Thief

The bottom layer
has been ignored and
cannot be recovered.

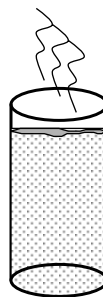


© 2004 Alpha Stat Consulting Company, All Rights Reserved.

Handling Error



Contamination

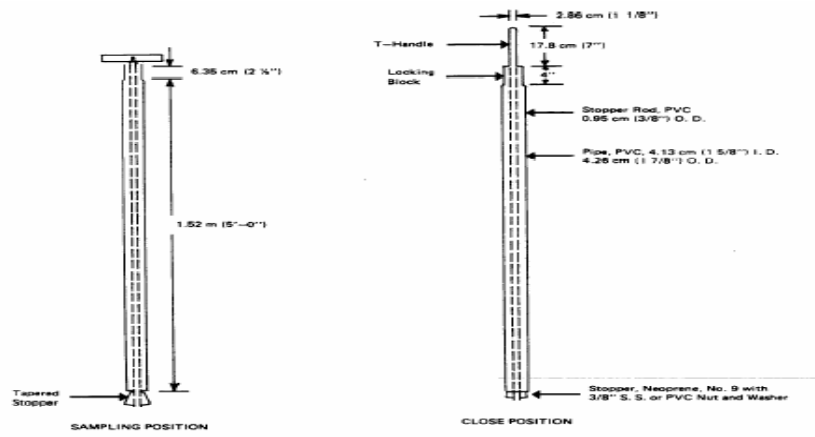


Loss

The Sample Integrity is not preserved.
(Chemists are a great resource in these situations.)

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

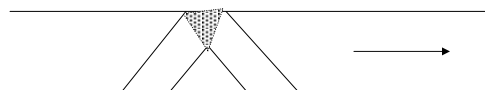
oliwasa



COMPOSITE LIQUID WASTE SAMPLER

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

The cutter does not go all the way through the stream.

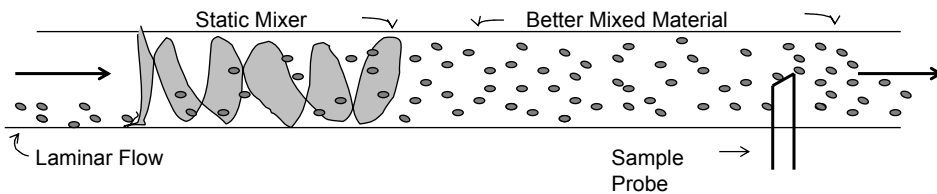


**Moving
Stream**

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

Sample Mixing Flowing Liquids or Gases

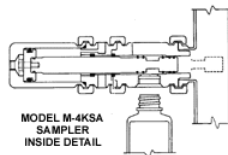
- A correct cross stream sample may be impossible to obtain.
- A static mixer can reduce the Grouping and Segregation Error.



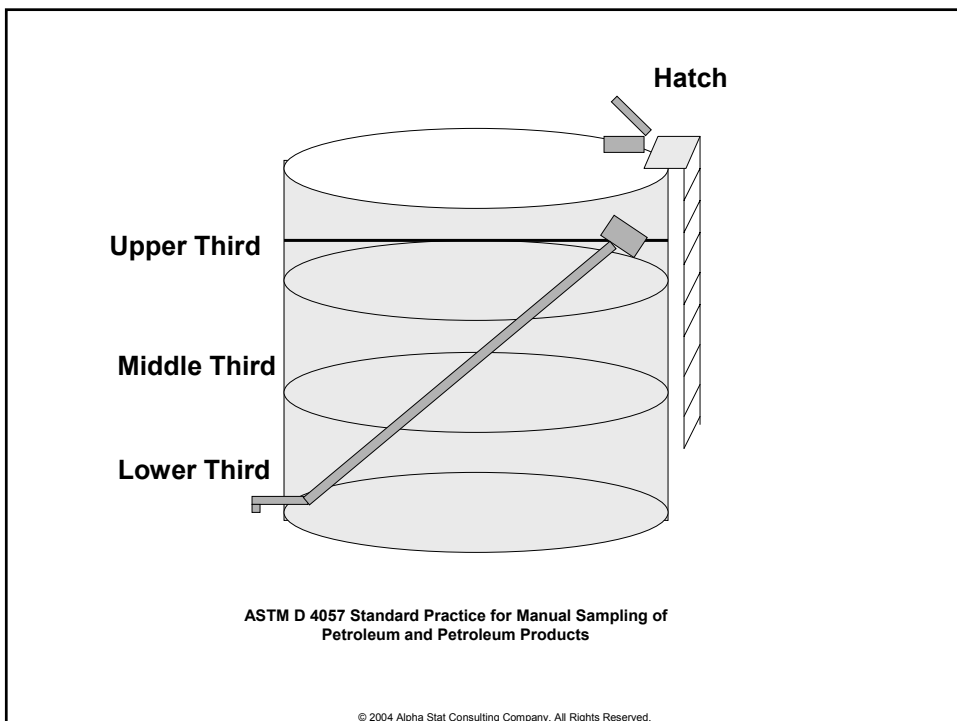
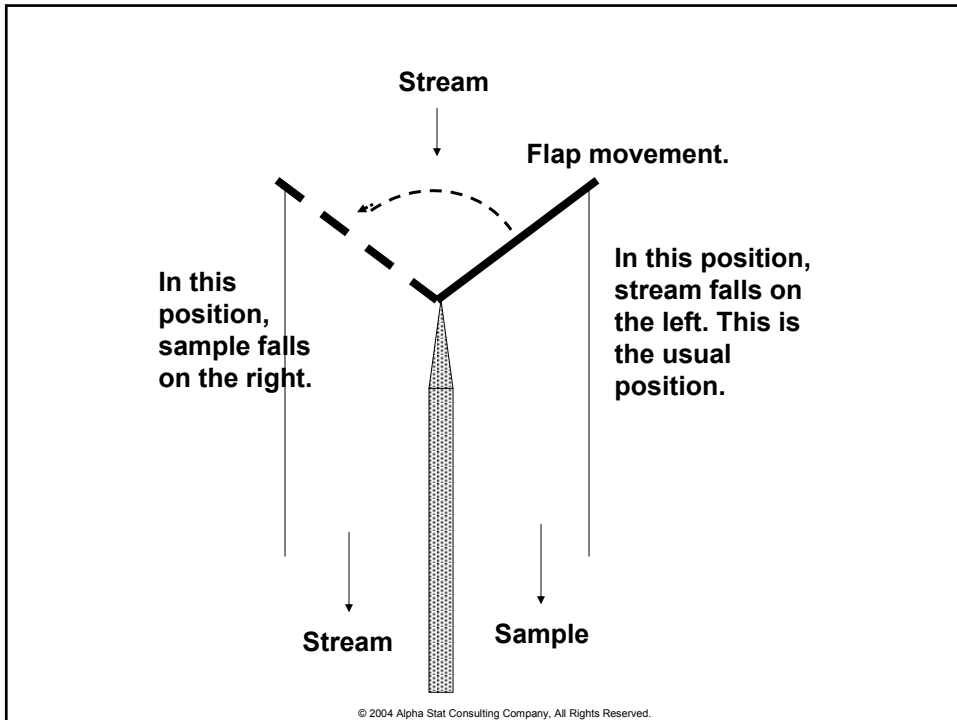
© 2004 Alpha Stat Consulting Company, All Rights Reserved.

The ISOLOK Model M-4KSA

www.thomasregister.com/olc/bristolequip/sanisamp.htm



© 2004 Alpha Stat Consulting Company, All Rights Reserved.



Hands-on Sampling Exercise

© 2004 Alpha Stat Consulting Company. All Rights Reserved.

Learning Objectives

- **State at least three problems with the sampling equipment used.**
- **Describe which method is better.**
- **Calculate the mean and standard deviation of the samples.**

© 2004 Alpha Stat Consulting Company. All Rights Reserved.

Plan

Members of the class will be divided into teams.

Each team will:

- **Get a bag with three different types of beans. Pretend you work in the lab, so this bag is your Lot (or population) of material.**
- **Use a particular method to sample the bag, as given by the instructor.**

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

Instructions

- 1. Sample the bag.**
- 2. Separate the bean types in the sample.**
- 3. Determine and record the percent weight for each type of bean.**
- 4. Return the sample to the lot.**
- 5. Repeat steps 1-4 twice, for a total of three experiments.**
- 6. Compute the average and standard deviation for each bean type using results from the three samples.**
- 7. Report your results to the instructor.**
- 8. Identify Delimitation, Extraction, and Handling errors. Be prepared to present to the class.**

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

Work Sheet Formulas

SAMPLE		Bean Type			SUM
		Lima	Pinto	Lentil	
1	Weight (W)	W_{L1}	W_{P1}	W_{I1}	$*W_1$
	% wt. (C)	$*C_{L1}$	C_{P1}	C_{I1}	
2	Weight	W_{L2}	W_{P2}	W_{I2}	W_2
	% wt.	C_{L2}	C_{P2}	C_{I2}	
3	Weight	W_{L3}	W_{P3}	W_{I3}	W_3
	% wt.	C_{L3}	C_{P3}	C_{I3}	
Summary	Ave. % wt.	$*C_L$	C_P	C_I	
	SD % wt.	$*SD_L$	SD_P	SD_I	

* Example Formulas

$$W_1 = W_{L1} + W_{P1} + W_{I1}$$

$$C_{L1} = 100 \times W_{L1} / W_1$$

$$C_L = (C_{L1} + C_{L2} + C_{L3}) / 3$$

$$SD_L = \text{SQRT}\{[(C_{L1} - C_L)^2 + (C_{L2} - C_L)^2 + (C_{L3} - C_L)^2] / 2\}$$

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

Work Sheet

SAMPLE		Bean Type			SUM
		Lima	Pinto	Lentil	
1	Weight (W)				
	% wt. (C)				
2	Weight				
	% wt.				
3	Weight				
	% wt.				
Summary	Ave. % wt.				
	SD % wt.				

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

Impact on Statistical Data Quality

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

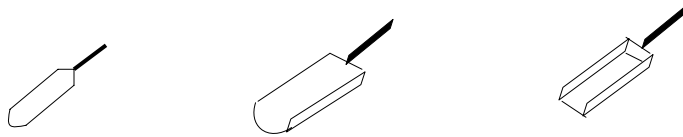
Experiments

Journal of Chemometrics, 2002, Vol. 16, pp 321-328
"Gy Sampling in experimental studies. 1. Assessing soil splitting protocols"
by Gerlach, Dobb, Raab, and Nocerino

- **Layers of sand, NaCl, magnetite.**
- **Six lab sampling methods.**
- **Riffle splitter performed the best overall.**

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

Scoops



© 2004 Alpha Stat Consulting Company, All Rights Reserved.

Coning and Quartering

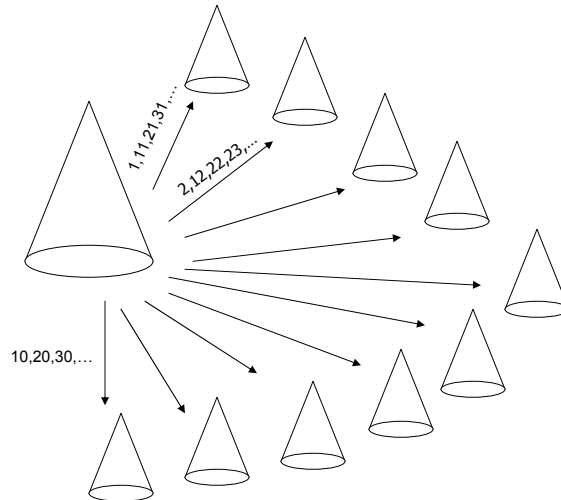


HM-275
SAMPLE QUARTERING KIT
ASTM C 109, C 702; AASHTO T248
www.globalgilson.com/index.asp

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

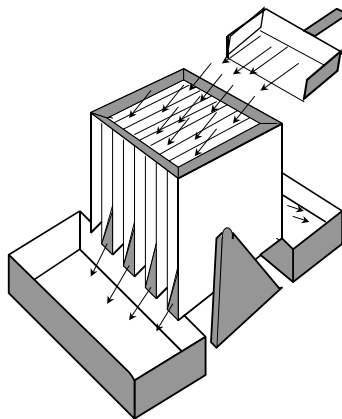
Fractional Shoveling

Move the entire lot to smaller piles and then select one at random for the sample.



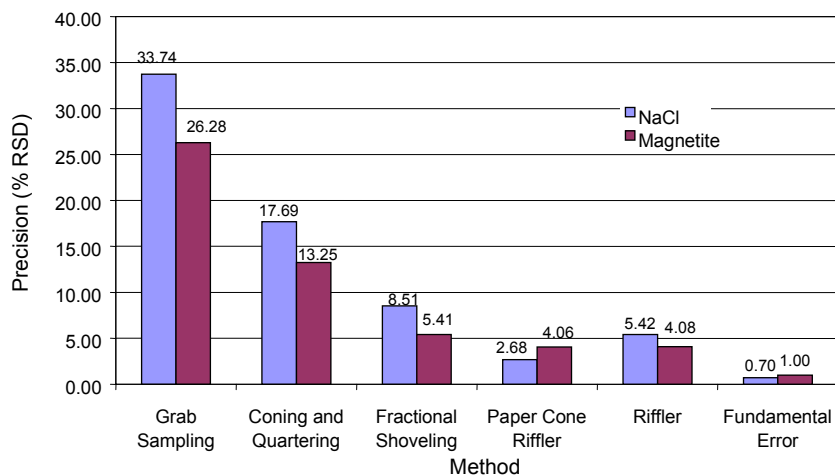
© 2004 Alpha Stat Consulting Company, All Rights Reserved.

Riffle Splitter



© 2004 Alpha Stat Consulting Company, All Rights Reserved.

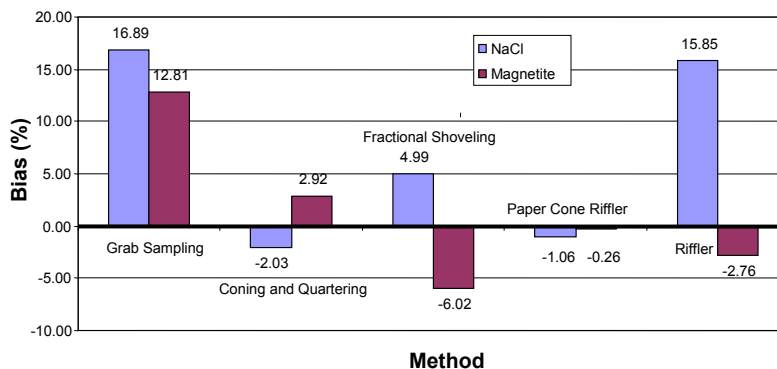
Precision of Subsampling Methods



Journal of Chemometrics, 2002, Vol. 16, pp 321-328
 "Gy Sampling in experimental studies. 1. Assessing soil splitting protocols"
 by Gerlach, Dobb, Raab, and Nocerino

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

Bias of Subsampling Methods



Journal of Chemometrics, 2002, Vol. 16, pp 321-328
 "Gy Sampling in experimental studies. 1. Assessing soil splitting protocols"
 by Gerlach, Dobb, Raab, and Nocerino

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

References

Gerlach, Robert W., Dobb, David E., Raab, Gregory A., and Nocerino, John M. (2002). "Gy sampling theory in environmental studies. 1. Assessing soil splitting protocols," *Journal of Chemometrics*, Vol. 16, pp 312-328.

Gerlach, Robert W. and Nocerino, John M. (2003). "Guidance for Obtaining Representative Laboratory Analytical Subsamples from Particulate Laboratory Samples," EPA/600/R-03/027, November 2003 Pre-Issue.

Gy, Pierre M. (1992). *Sampling of heterogeneous and dynamic material systems: theories of heterogeneity, sampling and homogenizing*, Amsterdam: Elsevier, 653 pages.

Myers, Jeffrey C. (1997). *Geostatistical Error Management: Quantifying Uncertainty for Environmental Sampling and Mapping*, New York: Van Nostrand Reinhold, 571 pages.

Pitard, Francis F. (1993). *Pierre Gy's Sampling Theory and Sampling Practice: Heterogeneity, Sampling correctness, and Statistical Process Control*, Second Edition, Boca Raton: CRC Press, 488 pages.

Smith, Patricia L. (2001). *A Primer for Sampling Solids, Liquids, and Gases: Based on the Seven Sampling Errors of Pierre Gy*, Philadelphia: The Society for Industrial and Applied Mathematics, 96 pages.

Smith, Patricia L. (2001). Review of Geostatistical Error Management, *Technometrics*, Vol. 43, No. 2, pp. 238-239.

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

Summary

Your decisions are only as good as your data.

Your data are only as good as your samples.

Your samples are only as good as the correctness of your sampling systems.

The correctness of your sampling systems is only as good as your audit and assessment of them.

© 2004 Alpha Stat Consulting Company, All Rights Reserved.

Ave (sd)	Method/Group	Limas	Pintos	Lentils
1	Scoop	41	25	34
	Keas	3.6	2.6	3.5
2	Alt. Shov.	46	26	28
	Koalas	3.5	2.5	4
3	Frac. Shov.	51	29	20
	Kiwis	1.2	1.7	1.2
4	Slabcake	40	26	34
	Kangaroos	1.7	0.58	1.53
5	Cone and Quarter	43	25	32
	Kakapo	7	5.6	7.1
6	Pour	46.3	21.1	32.5
	Kauri	2.5	2.1	3.2
	TRUE	42	26	32

Practical Applications and Benefits of ISO 9001:2000 to Current Quality Management Systems

Clyde Hedin, CQA

Roger Kell, CQA

Art Clarke

Garabet Kassakhian, Ph.D.

Roger Tokarz, CCAS

Quality Assurance Technical Support Program

Shaw Environmental, Inc. Las Vegas, Nevada 89120

John Nebelsick

U.S. Environmental Protection Agency

**U.S. Environmental Protection Agency 23rd National Conference on
Managing Environmental Quality Systems
Tampa, Florida April 16, 2004**



1

Introduction

✓ Four ISO 9000 topics in today's workshop:

1. Management Review
2. Customer Focus
3. Supplier Selection and Control
4. Training



2

EPA Quality Assurance Technical Support (QATS) Program

- ✓ Shaw's QATS contract:
 - ✓ Supports the EPA Analytical Services Branch (ASB) of the Office of Superfund Remediation and Technology Innovation (OSRTI).
 - ✓ EPA ASB manages the Contract Laboratory Program (CLP)
 - ✓ The QATS contract includes 5 main task areas:
 - 1) Performance Evaluation Samples and Reference Materials
 - 2) Tape and Data Audit
 - 3) On-site Audits
 - 4) Methods Development
 - 5) Logistical and Administrative Support
- (see handout #1)*

3

EPA Quality Assurance Technical Support Program

- ✓ In November 2000 EPA required QATS to become certified to ISO 9000 within 1 year.
- ✓ QATS achieved QMS certification to the ISO 9002:1994 standard on October 11, 2001 and upgrade certification to the ISO 9001:2000 standard on May 1, 2003.
- ✓ QATS has an excellent track record for registration and surveillance audits.
- ✓ 9 CQAs, 10 trained ISO 9000 Lead auditors

4

ISO and the ISO 9001:2000 Standard

- ✓ ISO International Organization for Standardization
 - ✓ “ISOS” = equal
 - ✓ World’s largest supplier of standards
 - ✓ Since 1947 has published 13,700 international standards
- ✓ Worldwide federation of national standards bodies
 - ✓ Comprised of National Standards Institutes from member countries
 - ✓ Currently represented in 148 countries (1)

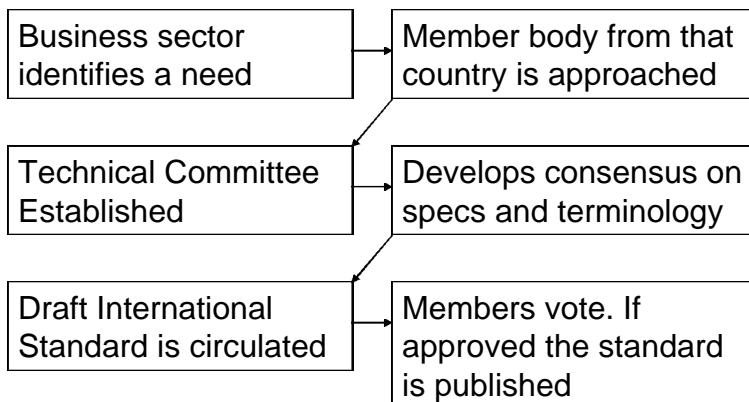
1. <http://www.iso.ch/iso/en/aboutiso/introduction/index.html>



5

ISO and the ISO 9001:2000 Standard

- ✓ Development of ISO standards is market driven process.



6

ISO and the ISO 9001:2000 Standard

- ✓ Purpose is to create worldwide standards for processes and products. ISO standards:

Improve product

- Quality
- Safety
- Reliability
- Efficiency
- Inter-changeability

Benefits

- Industry
- Suppliers
- Governments
- Trade
- Consumers
- Society



7

ISO and the ISO 9001:2000 Standard

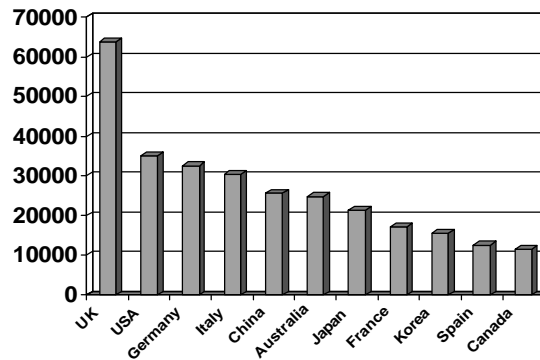
- ✓ The US member body is the American National Standards Institute (ANSI). The American Society for Quality (ASQ) is an organization accredited and used by ANSI to develop standards.
- ✓ ISO standards adopted by the US are designated "American National Standards."
- ✓ ISO 9000 – issued in 1987, slightly revised in 1994, and much more significantly revised in 2000.



8

ISO and the ISO 9001:2000 Standard

- ✓ 408,631 ISO 9000 certifications worldwide as of December 2000 (2)



2. The ISO Survey of ISO 9000 and ISO 14000 Certificates – Tenth Cycle, January 2003.



9

ISO and the ISO 9001:2000 Standard

- ✓ Motivations for seeking ISO 9000 certification (3)
 - ✓ Survey 1999-2000
 - ✓ 5398 firms, 15 countries, various business sectors
 - ✓ By both country and business sector:
 1. Quality improvements
 2. Corporate image
 3. Marketing advantage
 4. Customer pressure

3. Global Perspectives on Global Standards, ISO Management Systems – January-February 2003.



10

ISO and the ISO 9001:2000 Standard

- ✓ The current ISO 9000 standard is the “ANSI/ISO/ASQ Q9001:2000 Quality Management Systems – Requirements”
- ✓ ISO 9001:2000 is supported by 2 relevant documents
 - ✓ ANSI/ISO/ASQ Q9000-2000 Quality Management Systems – Fundamentals and Vocabulary
 - ✓ ANSI/ISO/ASQ Q9004-2000 Quality Management Systems – Guidelines for Performance Improvement
- ✓ A QMS can be certified **ONLY** to the ISO 9001:2000 standard



11

ISO and the ISO 9001:2000 Standard

- ✓ ISO 9000:2000 series of standards are based on 8 quality management principles *(see handout #2)*:
 1. Customer Focus
 2. Leadership
 3. Involvement of People
 4. Process Approach
 5. System Approach to Management
 6. Continual Improvement
 7. Factual Approach to Decision Making
 8. Mutually Beneficial Supplier Relationships



12

ISO 9001:2000 Principles Applicable to Quality Management Systems

- ✓ ISO 9001:2000 characteristics that may not apply to all Quality Management Systems:
 - ✓ Establishment of process approach based on the use of process inputs and outputs
 - ✓ Continual improvement and effectiveness assessments
 - ✓ Periodic third party surveillance audits



13

ISO 9001:2000 Principles Applicable to Quality Management Systems

- ✓ ISO 9001:2000 requirements applicable to all Quality Management Systems:
 - ✓ Management Review
 - ✓ Customer Focus
 - ✓ Supplier Evaluation and Control
 - ✓ Training Program



14

Management Review

Clyde Hedin, QATS Program Manager

Shaw Environmental, Inc.
Quality Assurance Technical Support Program
Las Vegas, Nevada



15

Management Review - Requirements

ISO 9001:2000 Section 5.6 - Management Review

“Top management shall review the organization’s quality management system, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.”

“Records from management reviews shall be maintained.”



16

Management Review - Requirements

- ✓ Section 5.6.2 (Review Input) and Section 5.6.3 (Review Output)
- ✓ Inputs
 - ✓ Progress against Objectives of Quality
 - ✓ Results of internal audits, customer feedback, corrective actions, etc.
- ✓ Outputs
 - ✓ Any decisions and actions identified to improve the effectiveness of the QMS, products, and resource needs



17

Management Review – Process Flow

ISO 9001:2000 Process Flow Diagram



18

How to Organize Management Review

- ✓ Frequency?
 - ✓ Can vary, depending on the needs and maturity of the QMS
- ✓ Who Participates?
 - ✓ Depends on the size of the organization.
 - ✓ All top management including the ISO management representative or quality assurance/quality control manager (for non-ISO QMS) should be required to attend.



19

How to Organize Management Review

- ✓ Fundamental Requirements
 - ✓ Set up QMS with measurable Objectives of Quality (*see handout #4*)
 - ✓ Have draft management review records prepared 1 week in advance. At a minimum, these records should include:
 - ✓ Data illustrating performance against objectives of quality (*see handout #5*)
 - ✓ Data showing continual improvement (*see handout #6*)
 - ✓ Data showing effectiveness of QMS for essential elements including internal audits, corrective and preventive actions, and customer feedback. (*see handouts #7-9*)
 - ✓ (show example of MR records)



20

How to Organize Management Review

- ✓ Suggested Tips for an Effective Management Review
 - ✓ Prepare a comprehensive agenda with assignments for management and task leaders. (see handout #10)
 - ✓ Provide draft MR records to attendees in advance.
 - ✓ Tape record the meeting to allow accurate reproduction of the minutes.
 - ✓ Management should ensure the agenda topics stay on schedule. Let everyone be heard, but keep the meeting on schedule. Have lunch brought in to minimize disruptions.

21



22

How to Organize Management Review

- ✓ Suggested Tips for an Effective Management Review (cont'd)
 - ✓ Record action items on a whiteboard or chalkboard as they are brought up. Finalize at the end of the meeting.
 - ✓ Encourage participation from all attendees, particularly when soliciting ideas for improving QMS processes.
 - ✓ Finalize and distribute the management review records to attendees within 30 days following the meeting.
 - ✓ Management must assign the action items (output) to individuals with deadlines to ensure they are completed (*see handout #11*).



23

Benefits of Management Review

- ✓ Results in process improvements
 - ✓ Trouble spots are identified
 - ✓ Action items are initiated
- ✓ Improves products and services
- ✓ Improves internal communication
- ✓ Identifies resource needs
- ✓ Extremely beneficial for registration/surveillance audits
- ✓ Improves and enhances Customer Focus



24

Benefits of Management Review

Questions?



25

Customer Focus

Clyde Hedin, CQA

Art Clarke, Database Programmer

Shaw Environmental, Inc.

Quality Assurance Technical Support Program

Las Vegas, Nevada

26

Customer Focus - Requirements

ISO 9001:2000 Section 5.2 Customer Focus

“Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).”

ISO 9001:2000 Section 7.2.1 Determination of requirements related to the product

“The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use.”



27

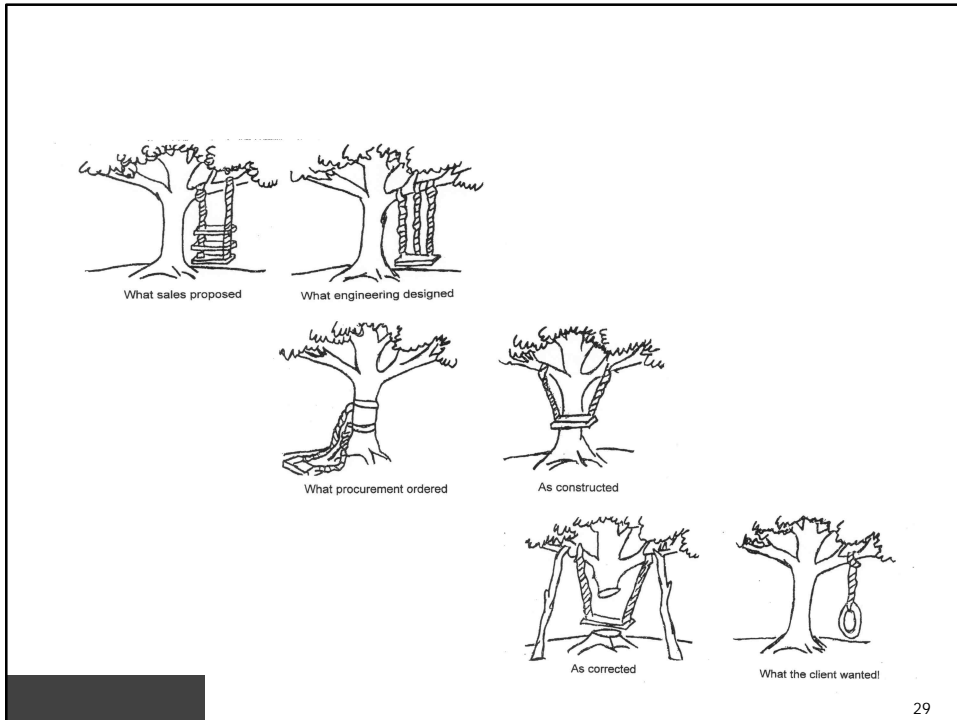
Customer Focus - Requirements

ISO 9001:2000 Section 8.2.1 Customer Satisfaction

“As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.”



28



Customer Focus - Challenges

- ✓ Challenges:
 - ✓ How do we determine if customer requirements (especially those not stated) are met?
 - ✓ How do we monitor information related to customer perception and customer satisfaction?
 - ✓ How do we establish a system of enhancing customer satisfaction by continual improvement?
- ✓ All are accomplished through customer communication, customer feedback, corrective actions, and preventive actions.



Customer Focus Customer Communication

- ✓ A documented system of client communication:
 - ✓ Ensures products and services meet customer requirements
 - ✓ Ensures contractual issues/questions are addressed
 - ✓ Allows both staff and management to review positive and negative customer feedbacks
 - ✓ Helps ensure responses and/or deliverables to the client do not slip through the cracks
 - ✓ Meets the requirements of the ISO 9001:2000 standard



31

Customer Focus Customer Feedback

- ✓ Customer feedback is an essential part of continual improvement:
 - ✓ A documented system of recording positive and negative feedbacks meets both the standard requirements and business needs.
 - ✓ The documentation should be designed to contain sufficient categories to allow trending by product, process, and feedback type. (*see handout # 12*)



32

Customer Focus

Customer Satisfaction/Feedback

Shaw Environment & Infrastructure, Inc. – QATS

QATS CLIENT SATISFACTION/FEEDBACK DOCUMENTATION

Client Contact Name: ENV/ACC STAFF Contact Date: 11/13/02
 Client Telephone Number: (703) 603-3000 QATS Personnel: Clyde Hedlin

Topic Discussed: (TO, Task, specific deliverable, activity, etc.)
 Task Order 2003, Task 01, Distribute PESs and RMs - The CN instructions need to be updated.

Client Comment:
 [REDACTED] called on 11/13/02 to discuss: 1) There needs to be new instructions for the low-medium CN. The current instructions indicate SOW ILM01.0. 2) find out when this set of instructions were sent (QATS form 04-25-2001). The labs are claiming the instructions are incorrect, in that they do not indicate the use of 1.0 gram sample aliquots.

Action Taken:
☐ No follow-up action required
 Task: 2003 Task: 01 Type of: L.A.2-Q-X (See QOP-14-02)
 Order: Feedback:

Note that Dion and John Burns investigated the instructions. The instructions for QBs and pre-awards are different than these old instructions that were sent with PESs to the Regions. The old instructions contain reference to ILM01.0 and do not indicate the use of 1.0 sample aliquots for mid-distillations. An NCR was prepared and the old instructions were replaced.

☒ For follow-up, refer to NCR #: 274

Copies: ☐ Program Manager ☒ QAO ☐ Group Leader:
☒ Technical Archives ☒ DCO ☐ Task Leader:
☐ Other:

Name: Clyde Hedlin Date: 11/30/02
 Signature: [Signature] 11/30/02

33

Customer Focus

Corrective Actions

- ✓ A system for identifying non-conformances and applying Corrective Actions is required by all quality systems:
- ✓ Non-conformances can occur in response to negative feedback from the customer, identified from internal audits, or identified through self inspection.
- ✓ A documented system of non-conformance reports (NCRs) is required by the ISO 9000 standard.
- ✓ As with customer feedbacks, NCRs should be designed to contain sufficient categorization to allow trending by product, process, system, etc. (see *handout #13*).

34

Customer Focus

Non-Conformance Report

Shaw Environmental & Infrastructure, Inc. - QATS	
NONCONFORMANCE CORRECTIVE ACTION / PREVENTIVE ACTION REPORT	
Report No.: 274	<input checked="" type="checkbox"/> Corrective Action
<input type="checkbox"/> Preventive Action	<input type="checkbox"/> Follow-up to NCR No.
Task Order Name: Distribution and Maintenance of the Superfund PES/RM Inventory	Task Order No.: 03
Task Name: Distribution of PESs and RMs	Task No.: 03
Nonconforming Item: Cytoside Soil PES Instructions	Date of Occurrence: 11/13/02
<input checked="" type="checkbox"/> Product <input type="checkbox"/> Process <input type="checkbox"/> System	Date of Detection: 11/13/02
Person Detecting Item: USEPA/USEPA/USEPA, QATS personnel	
<input type="checkbox"/> Internal Audit <input type="checkbox"/> Self Evaluation <input checked="" type="checkbox"/> Customer Feedback	
NCR Issued to (if applicable):	
<p>DESCRIPTION OF NONCONFORMANCE, OR CAUSE FOR PREVENTIVE ACTION</p> <p>USEPA users of cytoside and PESs notified QATS of problems in the PES instructions (see attached e-mail and FAX). Specifically, the instructions did not include language for weighing out grams of soil for MED distillation which caused one of the CLP Lab/USEPA to complain that their results were misclassified as a result of the 1-gram instructions. These instructions were prepared and approved in 1999 under Work Assignment 4-07. The referenced LHM 1.5 SOW was an out-of-date CLP SOW even in 1999 at the time the instructions were written. Distillation of the 1 gram MED distillation and the reference to LHM1 were both mistakes which should have been corrected at the time the instructions were written and in subsequent writing of QP instructions which required for same samples.</p> <p>Associated ISO 9001 Element(s): E - Product Identification and Traceability, 5 - Document Control</p> <p>Governing QATS Reference Document: <input type="checkbox"/> Quality Manual <input checked="" type="checkbox"/> QOP <input type="checkbox"/> SOP <input type="checkbox"/> Other</p> <p>QATS Reference Document Name, Number and Relevant Section(s):</p> <p>QOP 08 for Product Identification, QOP 03 for Document Control, and SOPs 60-001 and 60-002 for Production of PESs are all applicable.</p> <p>Does QATS Reference Document Require Modification? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>RESOLUTION OF NONCONFORMANCE CORRECTIVE ACTION / PREVENTIVE ACTION</p> <p>Root Cause of Nonconformance (Provide full Reference as Applicable, "N/A" for Preventive Action):</p> <p>Although the QOPs and SOPs do not directly address PES instructions, distributing PESs to USEPA users under Task Order 03 requires accompanying instructions. These instructions are written by QATS during PES production and become controlled documents in the QATS system upon approval by the USEPA. The PES instructions are subject to revision and updates as needed. Initial mistakes occurred with these instructions and the necessary reviews and updates did not occur.</p> <p>Corrective and/or Preventive Action Proposed for Implementation On or Before (date): 12-14-2002 for PES/RM instructions; Next review cycle for QOPs and SOPs.</p> <p>Implementation date specified by (check only one): <input checked="" type="checkbox"/> Task Leader <input type="checkbox"/> Group Leader <input type="checkbox"/> Program Manager</p> <p>Several e-mail communications occurred between QATS and USEPA explaining the PES instructions (see attached). The cytoside and PES instructions have been revised to include 1 gram MED distillation and LHM1.2 (see attached Form 20, BOP/TOR12, 11-14-2002). Review of the instructions for other PESs and RMs are also in progress. The applicable QOPs and SOPs should be revised to include PES and RM instructions.</p> <p>Approvals (Sign, Date, and pass to the next person in line):</p> <p>Q Task Leader (signature): <i>H. J. [Signature]</i> <input checked="" type="checkbox"/> Group Leader <input type="checkbox"/> Program Manager <input type="checkbox"/> QAO <i>11-23-2002</i></p> <p><i>11-23-2002</i> <i>11-23-2002</i> <i>11-23-2002</i> <i>11-23-2002</i> <i>11-23-2002</i> <i>11-23-2002</i> <i>11-23-2002</i> <i>11-23-2002</i> <i>11-23-2002</i> <i>11-23-2002</i></p> <p>QAO CLOSURE OF NONCONFORMANCE CORRECTIVE ACTION / PREVENTIVE ACTION</p> <p>Customer Involvement: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>Customer Response: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>Follow-up Corrective Action Required: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>Follow-up NCR No.: <i>12-5-2002</i></p> <p>Approval (Sign and Date): QAO <i>G. H. Kowalski</i> <i>12-5-2002</i></p> <p><i>12-5-2002</i> <i>12-5-2002</i> <i>12-5-2002</i> <i>12-5-2002</i> <i>12-5-2002</i> <i>12-5-2002</i> <i>12-5-2002</i> <i>12-5-2002</i> <i>12-5-2002</i> <i>12-5-2002</i></p> <p>FOLLOW-UP OF EFFECTIVENESS OF CORRECTIVE / PREVENTIVE ACTION</p> <p>Effectiveness of Corrective / Preventive Action to be Evaluated On or Before (date): <i>March 14, 2003</i></p> <p>Effectiveness check date specified by (check only one): <input type="checkbox"/> Task Leader <input type="checkbox"/> Group Leader <input type="checkbox"/> Program Manager <input checked="" type="checkbox"/> QAO</p> <p>Effectiveness Check: <i>12-14-2002</i> <i>12-14-2002</i> <i>12-14-2002</i> <i>12-14-2002</i> <i>12-14-2002</i> <i>12-14-2002</i> <i>12-14-2002</i> <i>12-14-2002</i> <i>12-14-2002</i> <i>12-14-2002</i></p> <p>Corrective / Preventive Action Effective? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No - Follow-up NCR No.: <i>12-14-2002</i></p> <p>Evaluator (Sign, Date): <i>G. H. Kowalski</i> <i>3-14-2003</i></p>	

35

Customer Focus

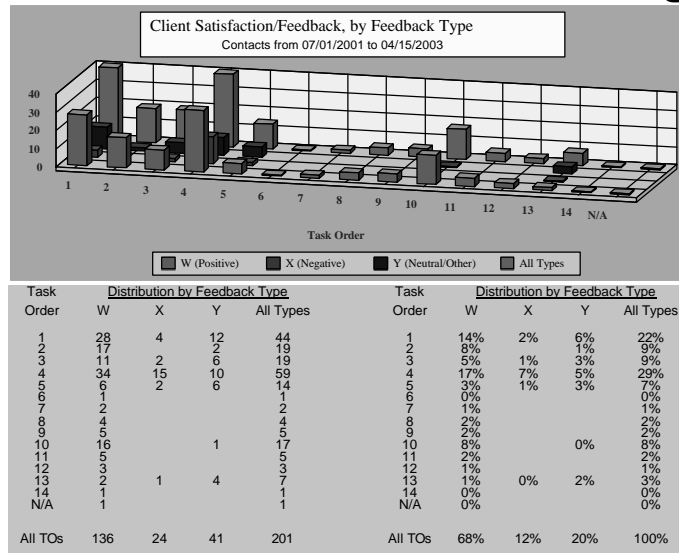
Preventive Actions and Continual Improvement

- ✓ Preventive Actions (PAs) are steps taken to prevent non-conformances from occurring.
- ✓ PAs can also be considered continual improvements to processes, products, systems.
- ✓ Analysis of data to effect continual improvement is required by Section 8.5.1 of the ISO 9001:2000 standard.

36

Customer Focus

Customer Feedback Trending

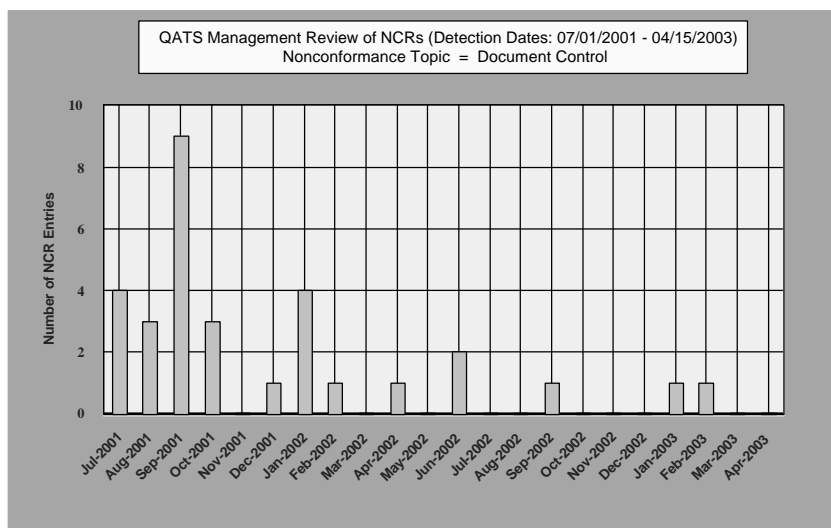


(see handout # 14)

37

Customer Focus

Non-Conformance Trending



(see handout # 15)

38

Customer Focus

Communication, Feedback, and Corrective Actions

- ✓ A system for documenting customer communications, customer feedbacks, and non-conformances can be cumbersome and time consuming.
- ✓ It is important to minimize the effort needed to record this information and to extract the data to monitor trends.
- ✓ To solve this we have developed the database application, Integrated Quality System (IQS).



39

Customer Focus

Integrated Quality System (IQS)

Art Clarke, Database Programmer
Integrated Quality System (IQS)

Shaw Environmental, Inc.
Quality Assurance Technical Support Program
Las Vegas, Nevada

40

Supplier Selection and Control

Roger Tokarz, CCAS
Manager, Contract/Procurement Administration

Shaw Environmental, Inc.
Quality Assurance Technical Support Program
Las Vegas, Nevada

41

ISO Purchasing Process - Product

ISO 9001:2000 Section 7.4.1

“The Organization shall ensure that the purchased product conforms to the specified requirements. The type and extent of control applied to the supplier and product shall be dependent upon the effect of the purchased product on the subsequent product realization or the **FINAL PRODUCT**.”

What does this mean?

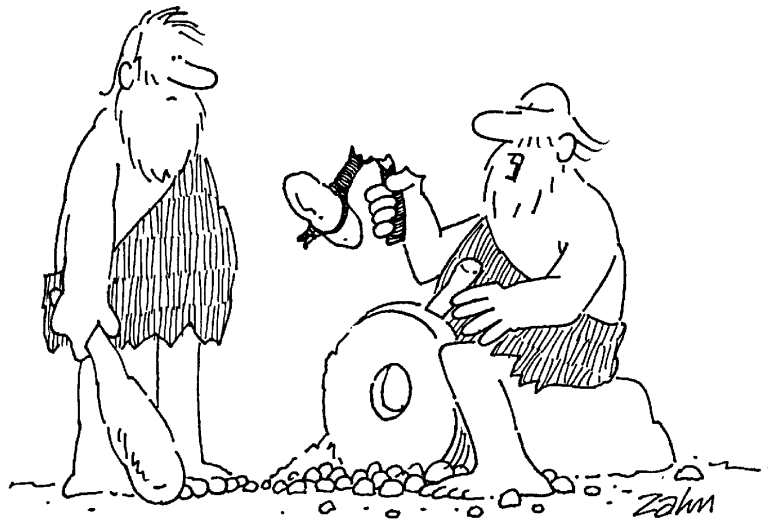
42

ISO Purchasing Process - Source

ISO 9001:2000 Section 7.4.1

"The Organization shall evaluate and select suppliers based upon their ability to supply product in accordance with the organization's requirements. **Criteria for selection, evaluation and re-evaluation** shall be established. Records of the results of evaluations and necessary actions arising from the evaluation shall be maintained."

43



"They don't make them the way they used to."

44

Supplier Classification Determination

CRITICAL

Product, service or commodity that could affect end item.

- ✓ Chemicals
- ✓ Components
- ✓ Subcontract work
- ✓ Software

NON-CRITICAL

Non-essential office or maintenance supplies.

- ✓ Cleaning supplies
- ✓ Office supplies
- ✓ Facility Maintenance
- ✓ Etc.

45

Supplier Evaluation Criteria

- ✓ Supplier capabilities
- ✓ Critical/non-critical product or need
- ✓ Previous similar experience
- ✓ Contractual subcontracting requirements
- ✓ Knowledge of FAR
- ✓ Procurement/Technical criteria

46

Supplier Evaluation Criteria – Critical Suppliers

Initial evaluation criteria for Critical Suppliers

Examples:

- ✓ Current ISO 9000 registration
- ✓ Supplier evaluation sample provided
- ✓ Acceptance of a quality system audit
- ✓ Completed pre-qualification questionnaire
- ✓ Performance history competitive price

47

Supplier Evaluation Documentation

- ✓ Evaluations conducted annually
- ✓ Results of evaluation documented (*see handout #16*)
- ✓ Three outcomes:
 - ✓ APPROVAL - Satisfactory completion of the Initial Supplier section.
 - ✓ RETENTION – Satisfactory completion of annual re-evaluation.
 - ✓ REMOVAL – Stated reasons for removal (Out of Business, Substandard Performance/ Product, No Longer Needed, etc.).

48

Approved Supplier Listing – Critical Suppliers

Critical Supplier list contains the following:

- ✓ Supplier name
- ✓ Small business classification
- ✓ Product/service category
- ✓ Internal approval ID number
- ✓ Area of utilization
- ✓ Signatures of approvers

(see handout #17)

49

Approved Supplier Listing – Non-Critical Suppliers

Non-Critical Supplier list contains the following:

- ✓ Supplier name
- ✓ Small business classification
- ✓ Internal approval ID number
- ✓ Task Order utilization
- ✓ List of approvers

(see handout #18)

50

Locating Qualified Suppliers

Difficulty in finding qualified sources occur because:

- ✓ Contract/Customer specifications
- ✓ Meeting technical requirements
- ✓ Meeting procurement criteria
- ✓ Cost, price, schedule, and
- ✓ Small business subcontracting goals.

51

Locating Qualified Suppliers (Cont'd)

- ✓ Small Business Administration (SBA)
- ✓ Small Business Development Center (SBDC)
usually associated with local university or college
- ✓ Chambers of Commerce, (City, State, Ethnic, etc.)
- ✓ Manufacturing Assistance Program (MAP)
also associated with local university or college
- ✓ Service Corps Of Retired Executives (SCORE) usually affiliated with local SBA Office

52

Locating Qualified Suppliers (Cont'd)

- ✓ Central Contractor Registration (Federal)

www.ccr.gov

- ✓ Association of Procurement Technical Assistance Centers

www.aptac-us.org

- ✓ SBA Procurement Website

www.pro-net.sba.gov

contain links to qualified supplier data bases to assist in meeting your subcontracting goals

53

RESULTS – Control of Outsourced Processes

The controls established by the pro-active steps of this procurement process ensure the scope of all outsourced work performed by non-organizational personnel meet or exceed the needs of your Customers resulting in:

- ✓ Product quality
- ✓ Schedule adherence
- ✓ Cost and price controls
- ✓ Total customer satisfaction

54

Supplier Selection and Control - BENEFITS

- ✓ Contractual adherence
- ✓ Cost and schedule control
- ✓ No surprises
- ✓ Less rework/rejected products
- ✓ Annual evaluations keep supplier performance at a high standard
- ✓ Process control establishes a continual improvement relationship between the Supplier, Organization and Customer

55

Supplier Selection and Control

Questions?

56

Training Program:

Requirements

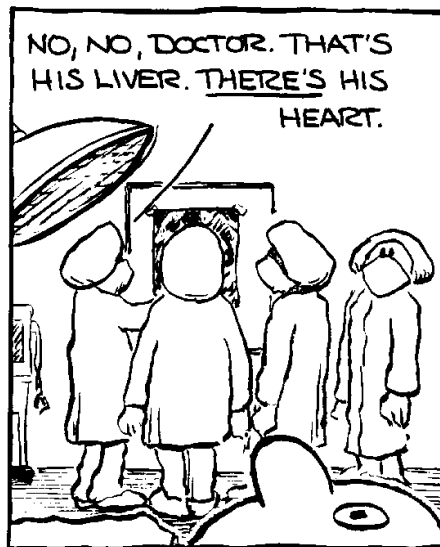
Components

Benefits

Roger A. Kell, CQA
Shaw Environmental, Inc.
Quality Assurance Technical Support Program
Las Vegas, Nevada



57



58

Training Requirements

- ✓ ISO 9001:2000 Section 6.2.2:
 - a) Determine competence for personnel
 - b) Provide training
 - c) Evaluate effectiveness
 - d) Ensure personnel awareness
 - e) Maintain appropriate records

59

Training Components

- ✓ Training Needs Assessments (*see handout #19*)
- ✓ Individual Training Records
- ✓ OJT
- ✓ Training Modules
- ✓ Position Descriptions
- ✓ Training Matrices (*see handout #20*)
- ✓ Miscellaneous: External Training, *Curriculum Vitae*, Resume, Certifications, Registrations, etc.

60

Training Needs Assessment

- ✓ Summary of requirements for position
- ✓ Requirements derive from:
 - ✓ Position Description
 - ✓ Training Matrices:
 - ✓ Main
 - ✓ Required reading
 - ✓ OJT
 - ✓ H&S
 - ✓ Recurrent

61

Training Records

- ✓ Specific to staff member
- ✓ Contains completed:
 - ✓ Training Needs Assessment(s)
 - ✓ New Employee Orientation Checklist
 - ✓ Required Reading Acknowledgement(s)
 - ✓ Resume, *Curriculum Vitae*
 - ✓ Certifications, Registrations, etc.
 - ✓ OJT Forms

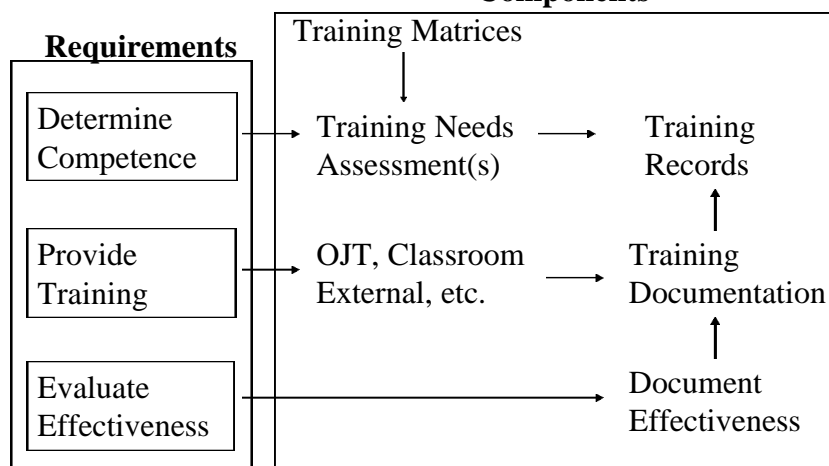
62

Training Effectiveness

- ✓ Demonstration of Proficiency:
 - ✓ Affects quality of products or services?
- ✓ Proficiency demonstrated by:
 - ✓ Written test
 - ✓ Performance of task
- ✓ Document effectiveness on training form

63

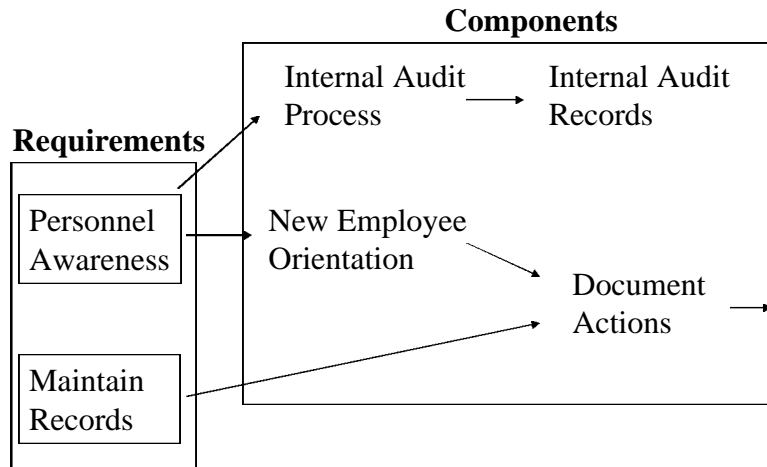
Training Requirements + Components



(see handout #19)

64

Training Requirements + Components



(see handout #20)

65

Training – Benefits (To the Organization)

- ✓ Complies with ALL requirements of Section 6.2.2 of ISO 9001:2000
- ✓ Adaptable to:
 - ✓ Requirements of any QMS
 - ✓ New training requirements
- ✓ Minimal effort to maintain
- ✓ Integral to other processes of organization

66

Training – Benefits (To the Customer)

- ✓ Products and Services - Minimal to zero error rate(s) due to training
- ✓ Product Quality - High
- ✓ Production Cost(s) - Minimized

67

Training Program Questions?

68

Conclusions

- ✓ Management Review
 - ✓ Improves processes, products/services
 - ✓ Focuses objectives, identifies action items
- ✓ Customer Focus
 - ✓ Communication key to meeting customer's needs
 - ✓ Improves customer relationships, adds follow-on business
- ✓ Supplier Selection and Control
 - ✓ Key to controlling input to product realization
- ✓ Training
 - ✓ Ensures customer product requirements are met

69

Acknowledgements

- ✓ US EPA Office of Superfund Remediation and Technology Innovation (OSRTI)
Analytical Services Branch (ASB)

70

Contact Information

Contact	Affiliation	Phone	E-mail
Clyde Hedin, CQA	Shaw	(702) 895-8711	Clyde.Hedin@Shawgrp.com
Art Clarke	Shaw	(702) 895-8714	Arthur.Clarke@Shawgrp.com
Roger Kell, CQA	Shaw	(702) 895-8701	Roger.Kell@Shawgrp.com
Garabet Kassakhian, Ph.D.	Shaw	(702) 895-8720	Garabet.Kassakhian@Shawgrp.com
Roger Tokarz	Shaw	(702) 895-8864	Roger.Tokarz@Shawgrp.com
John Nebelsick	USEPA	(703) 603-8845	Nebelsick.John@epamail.epa.gov